

REMARKS

This Response is to the final Office Action dated October 23, 2008. Claims 1 to 90 are pending and stand rejected. It is believed that no fee is due in connection with this Response, however, please charge Deposit Account No. 02-1818 for any fees deemed owed.

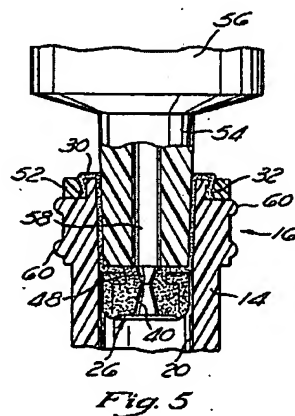
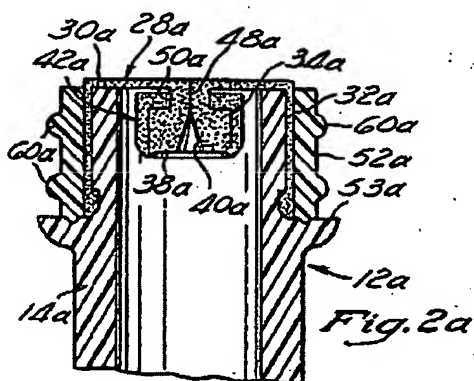
In the Office Action, claims 1 to 6, 8 to 13, 15 to 19, 21 to 25, 27 to 45, 47 to 51 and 53 to 90 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,470,319 to Mayer ("*Mayer*"). Claims 7, 14, 20, 26, 46 and 52 were rejected under 35 U.S.C. § 103(a) as being obvious over *Mayer* alone.

As discussed in a February 25, 2008, personal interview and in the previous Response, *Mayer* teaches a valve that is translated or distally compressed by the luer to allow a fluid pathway to open by either stretching the valve open due to the attachment of the valve to the housing or forcing the valve downward to expose a fluid pathway opening in a dilator. The present claims however set forth a different principal of operation, namely, one in which the luer tip is inserted into the valve to force or pry open an opening in the valve portion. It was discussed that such arrangement provides certain advantages, namely, less dead space and more effective use of the sealing capability of the valve material within a given housing size. The claims also specify that the resulting seal between the luer tip and the valve is the tip extending through an upper portion of the valve thereby forming a *radial* seal about the luer tip, which further and clearly distinguishes the claims over *Mayer*.

The Office Action States that *Mayer* under a broad reading of the reference teaches "*the second valve portion is forced radially open by the luer tip*". As shown in detail below, the portion of the valve taken by the Office Action to be or teach the claimed "second valve portion" is either *already* open prior to contact by the luer and thus *cannot* be opened by application of the luer or is stretched or displaced radially open by interactions between the septum and other components of the device and not the luer tip. The Office Action also appears to ignore language found in the claims, such as, "the luer tip is inserted downward into said opening in said housing and through said first portion *and within said second portion*" [emphasis added] found in claim 27 and "an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and *through said first portion into said second portion*" found in claim 47, for example. For these reasons and others set forth below, Applicants respectfully request reconsideration of the present claims.

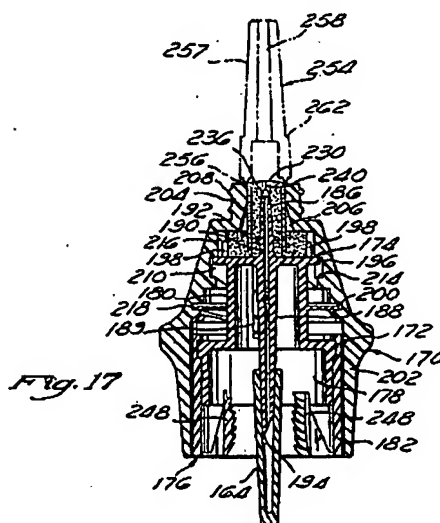
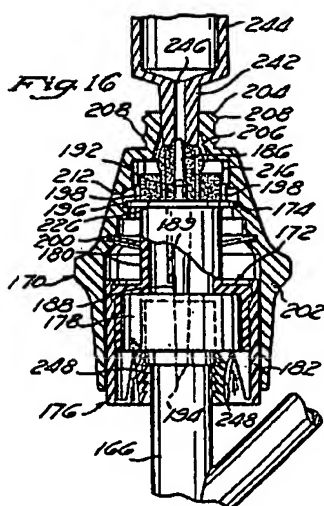
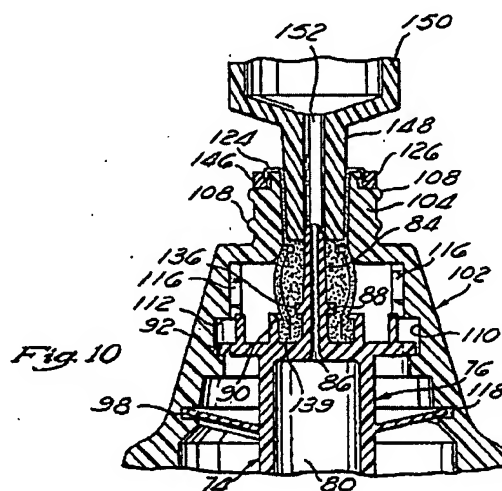
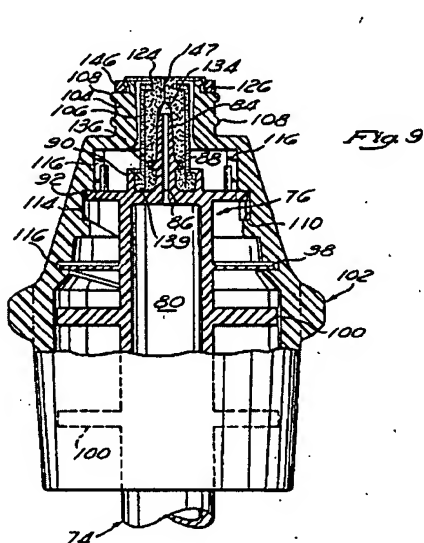
It is noted that throughout the Office Action, the Patent Office attempts to show anticipation by pointing to various combinations of elements over approximately three embodiments and does not focus on one embodiment to establish that all elements of a presented claim are found in that one embodiment. It is improper to borrow and steal elements from different embodiments of a reference to establish anticipation as confirmed in *Net Moneyin, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1371 (C.A.F.C., October 20, 2008) (wrong to combine two separate protocols for anticipation even where only slight differences exist between them).

Mayer discloses three different valves or reseal members 26, 120 and 220. As shown in Figs. 1 to 5 (Figs. 2A and 5 incorporated herein for convenience), member 26 is clearly insufficient to teach the claims because it does not show any second or third valve portion attached to (as called for in claims 1, 9 15, 21, 27, 34, 41, 47, 53); or abutted against (as called for in claim 79, 85) the device housing. Nor does member 26 teach the member being connected to the housing such that fluid does not flow into a space defined between the valve and housing, as generally called for in the independent claims.



Figs. 6 to 10 and Figs. 14 to 17 disclose second and third embodiments (Figs. 9, 10, 16 and 17 incorporated herein for convenience). Neither of these embodiments teaches a valve having an opening such that a luer tip extends through any upper portion of the valve. Instead an entirely different operation of these valves is clearly set forth in the specification. Referring to Column 12, lines 64 to 67 and column 13 lines 1 to 9 for the embodiment shown in Figs. 6 to 10 and Column 17 lines 29 to 42 for the embodiment shown in Figs. 14 to 17, the tip of the introducer device applies distally directed pressure to the top surface of the proximal valve portion causing the reseal member to distally advance within the central opening, thereby

causing the aperture to be forced over the dilator wherein the proximal tip of the dilator projection protrudes from the top surface and is received in the outlet passage of the introducer device. Thus, the tip of the introducer device contacts the top surface throughout the activation sequence to apply a distally directed pressure, and there is no penetration of the tip through any portion of the reseal member. In fact the dilator *prevents* the male luer from extending at all *into* any portion of the valve, let alone *through* a portion of the valve. Finally there is no need for the tip to penetrate the valve as the passageway within the dilator extends upward within the tip opening. In addition, there is no disclosure or suggestion that anything but this dilator is forcing any radial opening of the passageway through the reseal member.



Regarding the embodiment shown in Figs. 6 to 10, which uses the disclosed reseal member 120, the Office action cites element number 84 as allegedly teaching the claimed “second portion” of the claimed “resealable valve”. Element number 84 is actually the “dilator projection” of the embodiment of Figs. 6 to 10, but nevertheless shows an area of reseal member 120 that the Office Action cites as teaching the “second portion” of the claimed “resealable valve”. In *Mayer* there is no disclosure or teaching of the claimed “resealable valve,” which allows a luer to be (i) “*within said second portion*” of the valve as per claim 27 or (ii) moved “*into said second portion*” of the valve as per claim 47. Claims 27 and 47 accordingly recite additional patentable subject matter over *Mayer*. Moreover, it is respectfully submitted that due to the dilator, *Mayer* is physically incapable of having any portion of the introducer tip “inserted... within” (claim 27) or “inserted ... into” (claim 47) this element number 84 of the valve, nor is there any disclosure of a radial seal being formed about the luer tip by any portion of valve portion 84 as called for in claims 1, 9 and 15.

The application of *Mayer* is additionally misguided for the following reasons. First, piercing tip 194 of *Mayer* is not a luer tip as proposed in the Office Action at Page 3. Second, apparatuses 176 and 202 proposed to teach the claimed “annular flange” are actually part of two different structures of the embodiment of Figs. 14 to 17, neither of which alone or in combination is taught to provide or be an “annular flange”.

Third, Fig. 9 used to teach the claimed “first central passageway” is for a *different embodiment* than that of Figs. 14 to 17 used to teach the luer tip and the housing 270. Fig. 9 has a different housing than housing 270, which may be incompatible with the other features of the device of Figs. 14 to 17. -

Mayer also fails to teach numerous dependent claims. For example, claims 8, 55, 58, 61, 64, 67, 70, 73 and 74 further define the second valve portion to be in a stretched configuration. Portion 84 of reseal member 120 of *Mayer* is never in a stretched configuration.

Claims 56, 59, 62, 65, 68, 71, 74 and 77 further define the second portion of the valve to be stretched so as to hinder buckling of said second portion when the luer tip is inserted downward into said opening. Again, portion 84 of reseal member 120 of *Mayer* is never in a stretched configuration, let alone done so to prevent buckling.

Claims 57, 60, 63, 66, 69, 72, 75 and 78 further define the second portion of the valve to be stretched during assembly of the connector and attached to the housing in a stretched

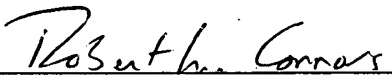
configuration. *Mayer* does not reach these claims. The Office action makes no attempt to address these or any of the dependent claims listed above.

Claims 28 and 35 also specify that upon removal of the luer tip, at least some fluid remaining in the second passageway is forced into the housing. The Office action makes no attempt to address claims 28 and 35. In the absence of a Notice of Allowance, Applicants respectfully request that a specific rejection of each of the above claims be made of record.

Applicants accordingly respectfully request reconsideration of the anticipation rejection of claims 1 to 6, 8 to 13, 15 to 19, 21 to 25, 27 to 45, 47 to 51 and 53 to 90, and respectfully submit that the patentability of those claims renders moot the obviousness rejection of claims 7, 14, 20, 26, 46 and 52. For all of the above-listed reasons, Applicants accordingly respectfully submit that this case should be reissued with the present claims.

Respectfully submitted,

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